



(SME) Market Development Project (ASME)

Armenian Honey Marketing and Beekeeping Improvement Project

Study Tour of Bulgarian Organic Honey Production

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TABLE OF CONTENTS

Bulgarian Honey Sector	3
Organic Honey in Bulgaria	4
Commercial Activity	5
Governmental Affairs and Associations	6
Representative Bulgarian Honey Producers and Processors:	6
Comparison of EU and US Organic Standards for Beekeeping and Honey	7
Strategy for Development of Armenian Organic Honey Sector	12
Attachment 1: Training and Study Tour booklet provided by VOCA Consult	13
Attachment 2: photo of 24 kg honey storage tins	36
Attachment 3: Photo of 300 kg honey storage barrels	37

<u>Introduction</u>: A group of 8 Armenian honey producers were led on a tour of Bulgarian honey production enterprises in August 2004, with special emphasis on organic honey production. Tour leaders were William Lord and Arsen Poghosyan.

Bulgarian Honey Sector

Production: There are 35 to 40,000 people involved in the beekeeping sector in Bulgaria. Most producers have 25-40 hives, though there is a growing sector of large commercial beekeepers (1000+ hives) along the Danube River. In a good year Bulgaria produces 15,000 tons of honey, 75% of which is exported. Primary export markets are the EU and the Middle East (5:1 ratio). High quality honey goes to the EU where standards are very high and lower quality honey is directed elsewhere. Approximately 20 companies are processing and selling honey on the internal and export market. Bulgaria has an international reputation as a producer of high quality honey.

<u>Distribution</u>: There are no state owned honey production or processing entities in Bulgaria. Most of the honey is produced by small beekeepers. Many processors have developed informal relationships with local beekeeping supply dealers that have direct contact with small beekeepers. Typically, processors with export orders contact local dealers specifying the quantity of honey needed, floral source, and price. The local dealer contacts the beekeepers, beekeepers deliver honey to the dealer, from whom the processor collects the consolidated order. The dealer may provide credit for the beekeeper in the spring to finance the summer crop, the principal and interest being paid with part of the honey crop. The problem with this system is inability to trace honey back to the original producer.

Quality control: Bulgaria is in the EU pre-accession SAPARD (Special Accession Programme for Agriculture and Rural Development) program with a target of full EU membership in 2007. According to the SAPARD program description "Food safety has a high priority in the EU. Food safety plays an important role in the accession preparations. The candidate countries need to ensure that they apply all food safety rules and that they have in place the appropriate control mechanisms."

(www.http://europa.eu.int/comm/enlargement/faq2.htm#Agriculture).

Honey processors visited by the Armenian delegation were in the process of adopting HACCP (Hazard Analysis and Critical Control Points) and ISO 9001 (International Organization for Standardization) standards. Bulgarian regulations have been adopted to reflect EU standards and are included in the Training and Study Tour document as attachment 1. To meet stringent EU standards beekeepers will need to use only registered drugs and chemicals for treatment of bee diseases, avoid contamination of honey by proper storage, and provide documentation so honey can be traced back to the producer in the event of problems. Standard honey storage containers in use in Bulgaria are 24 kg food grade tins with large tops (see attachment 2). Bulk storage is in 300 kg food grade barrels (see attachment 3).

Bulgarian laboratories are able to certify physical and chemical properties of honey, but outside (primarily German), internationally recognized ISO certified laboratories are used to test for antibiotic and miticide residues as well as C4 sugar adulteration. (C4 plants are corn (maize), sugar cane, and sugar beets; sources of processed sugar.) (It should be noted that Armenia already has ISO certified Ex-Lab, that can conduct the same analyses required by EU standards.) Samples are taken from 6-7 ton lots by taking individual samples from each 24 kg tin, homogenizing to form a composite, with 250 gram jars of the composite being sealed and shipped to the laboratory. Average prices for physical/chemical tests are \$375, and \$625 for antibiotic/sugar tests.

Organic Honey in Bulgaria

Production: There are approximately 15 organic honey producers in Bulgaria in 2004. Bulgarian organic beekeepers use integrated pest management to control honey bee pests and diseases. In particular, the varroa mite is controlled by a combination of drone brood trapping (immature drone brood is destroyed, killing mites) and use of a organic fumigant composed of 5 grams of menthol and 3 grams of thymol applied on an absorbent sponge that is placed in the hive. The menthol/thymol sponge gives 90% varroa control. (Armenian beekeepers have been taught the principles and practices of honey bee IPM.) Producers are organized into the Association of Organic Beekeepers, an NGO with an educational mission, and the Balkan BioHoney Cooperative for marketing. Organic production in 2004 is estimated to be between 10 and 30 tons. Organic honey production is regulated under Regulation # 35 of the Bulgarian Beekeeping Act (Appendix 1, pg. 9) and is based on EU Directive 209/91.

<u>Certification</u>: Organic certification is under development in Bulgaria in 2004. The Bulgarian organic certification agency is SGS Bulgaria. All organic certification that has been carried out in Bulgaria thus far has been by agencies outside of Bulgaria. This is due to the fact that Bulgaria doesn't have a local organic certifying body accredited by a third party internationally recognized organization. In addition, the country of destination for export usually requires the product to be certified by its own certification agency and standards, which usually costs much more than that of a local certifying body. Four different outside agencies (Greek, Canadian, Italian, Swiss) are certifying Bulgarian organic products at this time. These companies have branches in Bulgaria but use a foreign license for certification.

Cost for domestic organic certification in Bulgaria (SGS Bulgaria) is \$312 - \$500 per year. For foreign certification, costs are at least \$1250 plus expenses. Professor Karov, head of SGS Bulgaria, suggests that the best approach for organic honey certification is to form a union or association to split the cost of certification among the members, which is the approach being taken by the Bulgarian Association of Organic Beekeepers. Given the similar situation of Armenian producers, the same model could be used in Armenia for this purpose.

Organic Honey Sales: Noncertified organic honey is being sold in Bulgaria as "ecological" honey. The organic law in Bulgaria says that only organically certified products can be sold in the markets as organic and bear the name "biological" on the labels. Therefore, most of beekeepers used the word "ecological" on their labels, before they can afford to apply for organic certification. One processor noted that of his 6 honey product lines, biological honey was the fourth best seller in Bulgarian markets. Several large beekeepers and processors are in the early stages of organic certification and plan on selling certified "biological" honey on the domestic and export markets for a premium. The consensus was that the targeted markets are the EU and the US as well as EU and American tourists in Bulgaria

Commercial Activity

<u>Veterinary Drug Supply and Regulation:</u> Due to its pre-accession status, Bulgarian agricultural producers may only use plant and animal protection products that are certified by the EU. The Armenian beekeeping delegation met with Dr. Ivan Panchev and Dr. Filip Stanchev of Primavet Sofia, LTD, which manufactures and supplies 95% of the beekeeping medication market in Bulgaria. Primavet supplies a full range of standard beekeeping drugs and chemicals, and is developing products for certified organic production. Primavet is interested in doing business in Armenia and is willing to enter discussions with appropriate agencies to enter the Armenian market.

Queen Breeding: The Armenian delegation visited the National Queen Breeding Association's Queen Breeding Station in Plovdiv. The station is supported partially by the Bulgarian Ministry of Agriculture and partially through private sales of breeder queens. The station provides breeding stock to commercial queen producers in Bulgaria and commercial queen producers are required to belong to the Queen Breeding Association to produce and sell queens. The queen breeding station provides breeding stock to members and carries out quality control checks on commercial producers. Queens are selected for productivity and disease resistance. Breeder queens sell for \$4.80 and commercial queen producers sell queens for \$6.00. In 2004 the station had produced 20,000 queens through late August.

<u>Honey Prices 2004</u>: Because of the EU ban on Chinese honey, prices for Bulgarian honey in Europe have been good for the past two years. One small processor paid \$2 per kg in 2003, but is paying \$1.25 per kg in 2004 based on recent news that Chinese honey is being allowed back in Europe. Kiro Kirov is averaging \$10 per kg selling honey to tourists on the Black Sea resorts. One large processor is receiving \$2688 per ton for bulk honey exported to Italy in 300 kg barrels. Bulgarian honey processors expect a 40% price premium for certified organic honey. Retail price premiums in the US for organic honey range from 30 to 45%. The wholesale and retail organic honey market is in the early developmental phase, though a 20-50% premium is common for organic products in general.

Governmental Affairs and Associations

Beekeeping Associations: Bulgaria has one national beekeeping association that charges members a small membership fee based on numbers of hives owned (eg. \$3.75/50 hives). There are many local and regional associations affiliated with the national association. The mission of the association is education and representation of beekeeper interests with the government. There is a small professional beekeepers association and and an association of honey processors. The queen producers association referenced earlier is more of a commercial/regulatory association. Associations play an active role in beekeeping policy and regulation development in Bulgaria. According to a Ministry of Agriculture spokesperson "When big decisions are being made, the Ministry invites all of the associations in to help make the decisions." This policy closely follows recommendations of the EU Enlargement Programme.

Ministry of Agriculture: The main goal of the beekeeping section of the Bulgarian Ministry of Agriculture (MoA) is to help the development of the beekeeping sector and to help establish a national strategy for beekeeping in Bulgaria. Regulation is achieved through the Beekeeping Act and the Veterinary Act, both modeled on EU regulations. The MoA is supporting beekeeping development with SAPARD funds with two programs: 50% cost share of capital improvements and low interest loans (3%). Funds are targeted towards rural and mountainous regions, with minimum expenditures of \$1250 and a maximum of \$250,000 per project. Funds may be used for apiary development, bee hives, processing equipment and buildings, queens, storage, and labeling. Many applications have been received for the SAPARD program. As of August 2004, 78 projects have been approved in beekeeping for \$6,250,206. Of the 78 projects, 14 have been completed for an expenditure of \$81,250.

Beekeeping extension programs are carried out in Bulgaria as a part of the University research service. There are extension offices and agents in each of the 28 regions of Bulgaria.

The queen breeding station in Plovid is being supported with SAPARD funds with the goal of eventual privatization of that project.

Representative Bulgarian Honey Producers and Processors:

Bilbo Bee and Honey, Valeri Tzikov, owner, Varna: Bilbo sells 30 tons of honey per year in consumer packs in grocery stores in the Varna (Black Sea) region. Bilbo sells 6 different products, including varietal honey, comb honey, pollen and royal jelly products. Bilbo sells an organic honey as 'ecological' honey, which is his fourth best seller. He expects high profit margins from organic honey but prefers to sell organic honey to tourists in Bulgaria rather than to ship it to the tourists' home market.

Black Sea Bee Ranch, Kiro Kirov, Sunny Beach Bulgaria: Kiro specializes in sales to tourists at Sunny Beach and Nessebar region of Bulgaria. He supplies 45 stores in the

area and has honey stands in UNESCO World Heritage city of Nessebar. Kiro sells 25 different products including varietal honey, honey in ceramic honey pots (best seller), as well as pollen, propolis, and royal jelly products. He advertises on local access cable TV. Kiro has a beekeeping archeological museum at his bee ranch, conducts apitherapy, and serves (and sells) honey products at the ranch, including honey citrus drinks and honey wine.

Oberon-X Ltd, Sofia. Oberon is a large industrial food processor specializing in honey, rice, and pulses. They process 20 tons of honey per month for domestic and export market. Oberon packs honey under their own as well as private labels and exports in bulk (300 kg barrels). They are in the process of complying with HAACP regulations, and perform physical and chemical quality tests in an in-house laboratory. Oberon uses German and Italian labs for additional quality tests (antibiotics and chemicals).

Sizif JSC, Sofia. Sizif is a large vertically integrated bee and honey company. They own and operate approximately 5,000 hives in Danube region of Bulgaria. Sizif manufactures and sells a full range of beekeeping equipment. Sizif exports 1,000 tons of honey per year, 60% in bulk (300 kg barrels) and 40% in wide range of consumer packs for the domestic and export market under their own and private labels. They have an in-house lab for physical and chemical tests and use German labs for antibiotics and sugar analysis. Sizif is in the process of complying with HAACP and IOS 9001 regulations. Sizif has implemented a beekeeper training program (now supported by SAPARD) to train young people in professional beekeeping in order to replace older, retiring beekeepers with technically competent beekeepers who understand modern beekeeping and international honey quality standards.

(Exchange rate: \$1 = 1.6 Leva = €.80 Euro = 515 AMD Prices quoted in U. S dollars)

Comparison of EU and US Organic Standards for Beekeeping and Honey

The objectives of organic farming include application of production methods that do not damage the environment, more respectful use of the countryside, concern for animal welfare, and the production of high quality agricultural products. Both the EU and US organic standards consider honey bees to be livestock. Federal laws supercede state laws in the US while the EU consists of state governments, each of which can grant exceptions to established EU regulations.

EU organic beekeeping regulation: Part B of Annex I to Regulation (EEC) No. 2092/91 as amended on July 19, 1999 by Regulation (EC) No. 1804/1999 lays down minimum rules for organic livestock production (http://europa.eu.int/eur-ex/pri/en/oj/dat/1999/l_222/l_22219990824en00010028.pdf). The member states may adopt stricter rules (under article 12 of Regulation (EEC) No. 2092/91) concerning animals and animal products produced on their territory. Part C of Annex I of Regulation (EEC) No. 2092/91 specifically applies to beekeeping.

<u>US organic beekeeping regulation:</u> The United States Department of Agriculture (USDA) Agriculture Marketing Service (AMS) has established the National Organic Program (NOP). The National Organic Standards Board Apiculture Task Force has published a set of draft rules for apiculture primarily under section B205.240. For a full listing of US organic standards see: http://www.ams.usda.gov/nop, Program Standards, Regulatory Text Only.

<u>EU organic import standards</u>: "While organic standards have been set at the EU level, implementation and enforcement of the regulation is the responsibility of the individual member states. This member state responsibility also extends to imports of organic products. In order to import organic products, EU importers must work through their designated member state authority to obtain an import authorization. These authorizations are granted on a case-by-case basis, subject to the member state's review of two main elements:

- The organic standards and inspection measures applied by the certifier of the product; and
- The certifier's compliance with EN 45011 or ISO Guide 65

The importer must demonstrate that the product was produced according to standards equivalent to the EU standard. In addition, the importer must provide evidence that the certifier of the product has been accredited to EN 45011/ISO 65 by an authority recognized by the member state. Individual member states may have different criteria for judging compliance with these requirements."

(Http://www.usue.be/AGRI/organic.html)

According to the USDA FAS GAIN Report No. E34025, on June 24, 2004 the European Commission adopted the "European Action Plan for Organic Food and Farming" which, among other steps, proposes to: "Step up efforts to include third countries in the equivalency list, including on-the-spot assessments. Amend Regulation 2092/91, replacing the current national derogation for imports by a new permanent system making use of technical equivalency evaluations by bodies assigned by the Community for that purpose. This could include, following appropriate consultations, developing a single and permanent Community list of inspection bodies recognized as equivalent for their activities in third countries not already on the equivalence list. Continue to ensure that the definition of equivalence with third countries takes into account the different climate and farming conditions and the stage of development of organic farming in each country. Upon entry into force of this system, offer all imported products access to the EU logo." (USDA GAIN Report No. E34025)

US Organic Import Standards: According to the USDA NOP: "The National Organic Standards require all agricultural products sold, labeled or represented as organic in the United States be certified by a U.S. Department of Agriculture (USDA) accredited certifying agent.

However, in lieu of organic certification by a USDA accredited certifying agent, imported organic agricultural products may be sold in the United States if they have been certified and recognized through (1) a USDA recognition of conformity assessment or (2) an equivalency determination.

Under the recognition of conformity assessment option, imported organic agricultural product may be sold, labeled, or represented as organically produced if the product is produced and handled to the National Organic Standards and certified by an accredited certifying agent recognized by USDA. Recognition of certifying agents will be determined by USDA, based upon the request of a foreign government, that the foreign certifying agent's government is able to assess and accredit certifying agents as meeting the requirements of the USDA National Organic Program.

Imported organic agricultural product may also be sold, labeled or represented as organic when USDA has determined a foreign government's organic certification program to be equivalent to that of the NOP. Equivalent means that USDA has determined that a foreign government's technical requirements and conformity assessment system adequately fulfills the objectives of the Organic Food Production Act and its implementing regulations. Determinations of equivalency are the most complex and time-consuming types of import arrangements to establish."

(http://www.ams.usda.gov/nop/NOP/TradeIssues/importedorganic.html)

For purposes of comparison, organic standards are listed below with application to EU and US regulations:

Beekeeping and	EU Regulations	US Regulations		
Honey				
	CONVERSION			
Minimum conversion time	1 year, with all wax replaced, can add 10% new hives per year if wax is	1 year		
for beekeeping products	replaced			
Origin of stock	Not stated	From continuous organic or under organic management for last third of gestation		
Stock genetics	Disease resistant European breeds and local ecotypes	Should be disease resistant stock		
Queen wing clipping allowed	No	No		
Queen replacement	Yes	Yes		

allowed			
Drone brood destruction allowed	Yes	Yes	
Site selection	3 km radius essentially organic	3.2 km	
Site details	Map of apiary and forage area	Map of forage area, water source, distance from prohibited land uses.	
On-site inspections	Must allow	Must allow	
	RECORD KEEPING		
Organic plan required	Health passport required	Yes	
Maintain records	Detailed accounts must be kept to ensure traceability.	Annually, keep for 5 years	
Inspections	Required annually	Required for certification	
	FEEDING		
Only organic feed is allowed	Yes – organic sugar, honey, or molasses. Records required.	Yes – organic honey or sugar	
Timing of feeding	Only between last honey harvest and 15 days before first honey flow	Cannot feed less than 30 days before harvest	
'Split' organic and conventional operation allowed	Yes, if separated	Yes, if separated, comingling prevented	
I	DISEASE PREVENTION AND TREAT	MENT	
Is chemically synthesized allopathic treatment allowed	Yes, only as a last resort under veterinary supervision, then change wax, 1-year conversion period.	Only as last resort to save colony	
Is allopathic or antibiotic preventive treatment allowed	No	No	
Are homeopathic and phyto- therapeutic treatment	Yes, first line of treatment – see list of approved products	Yes – see list of approved products	

allowed?		
Can hives be allowed to die from disease	No	No
	EQUIPMENT	
Must organic wax be used	Yes	Yes
Is plastic allowed	No	No
Paint	Only "natural" materials	Oil based
Hive materials	Natural materials	Natural materials
Wax foundation	Certified organic, inspector can authorize non-organic wax during conversion period	Certified organic
	PROCESSING	
Equipment	Heating shall not exceed 45C, all food grade equipment	All food grade, document all heating of honey, no high pressure filtration
Cleaning and disinfection of equipment	See list of approved products, guidelines follow HAACP closely	Must follow Good Manufacturing Process guidelines
Pest control	Only approved materials – see list	No chemicals, only natural or mechanical means
	LABELING	
	Certificate and certifying authority, national organic symbol or EU organic symbol	Must be 100% organic, may use USDA organic seal, or seal of certifying agency
	CERTIFICATION	
Certification required	Yes	Yes
Exemptions allowed	No	Yes, if sales less than \$5000 per year
Prohibitions	Killing bees, use of synthetic repellents when taking honey	Killing bees, use of synthetic repellents
Hive management	Requening is allowed	Requeening is allowed

Hive movement	Coordinate with regulatory authority.	Document
Imports	Only allowed if third county has equivalent organic rules, list of approved countries is available. Imports must be covered by certificate of incounty agency, meet ISO 65 standards	Must meet US standards or equivalent
Logos	SCHALL FARMING	USDA ORGANIC

Strategy for Development of Armenian Organic Honey Sector

Short Term Strategy: Produce certified organic honey in Armenia in 2005

Steps: 1. Identify honey producers who want to produce certified organic honey.

- 2. Sign contracts with ECOGLOBE to officially begin 1 year conversion to organic status.
- 3. Work with ECOGLOBE to develop internationally recognized organic beekeeping and honey production standards for Armenia.
- 3. Identify markets (specific countries) for organic honey and determine the organic standards required by the individual country.
- 4. Implement organic beekeeping practices that meet the standards of the countries identified as the potential markets, including acquiring certified organic disease and pest control products as well as implementation of proper storage and processing techniques.
- 5. Be prepared to perform chemical and physical analysis of honey to certify that it meets standards and tolerances.

Mid-term Strategy: Expansion of Organic Honey Production and Marketing

Steps: 1. Form organic honey producer association for purposes of education, group certification, and advocacy

- 2. Pursue independent organic certification for association.
- 3. Expand production and marketing or organic honey.

Long Term Strategy: Consolidate organic processing and marketing to achieve economies of scale and sustainability.

Steps: 1. Assist private honey processor with compliance with organic processing requirements and market identification.

Attachment 1: Training and Study Tour booklet provided by VOCA Consult

BEEKEEPING IN BULGARIA

1. INTRODUCTION

1.1 Regulatory framework

The regulatory framework of bee keeping, production and distribution of bee products in Bulgaria includes:

- Bee keeping Act;
- Stock-breeding Act;
- Veterinary-medical Activity Act;
- Foods Act;
- Regulation for the requirements pertaining to bee honey designated for human use;
- Regulation No. 25 for the establishment of maximum allowable limits of residual substances in the formulation of veterinary-medical preparations of pharmacologically active substances in the ingredients of veterinary-medical preparations in raw materials and products of animal origin designated for human consumption;
- Regulation No. 30 for the prophylaxis of and fight against some infectious diseases on bees:
- Regulation No. 35 for the biological production of animal products and foods and their labelling;
- Bulgarian State Standard (BSS) 2673/89 and Industry Standard for some bee products.

1.2 Functions of bee keeping

Bee keeping practice brings to the front two functions:

PRODUCTION: Bee honey and bee products, queen-bees? swarms of bees;

POLLINATION: pollination activities on wild and cultivated vegetation - free of charge, and paid in rare cases. It is scientifically grounded that these activities have greater economic importance than production of bee products and immeasurable importance for the biological equilibrium in nature.

1.3 Organic bee keeping

This is an application of bee keeping, which is aimed at:

MAXIMUM POSITIVE IMPACT on the environment – mainly via pollination of bees and the activities of bee-keepers – afforesting, cultivation of deserted lands, production of bee products, etc.;

MINIMUM NEGATIVE IMPACT on bee products – bee-keepers' striving to make pure bee products as closer to that bees make themselves.

Combination of these two impacts forms the so-called **PRINCIPLE OF POSITIVE DISCRIMINATION** in organic bee keeping [1]. The meaning of this concept is bee-keepers' activity to be as closest to what nature has created and developed

over thousands of years. To make popular and employed the good practices for human life and nature equilibrium and to discard or limit the harmful impacts on the quality of bee products.

1.4 Reference for the production of quality bee products

The reference for quality bee products arises from the fact that the bee-keeper voluntarily agrees to respect these terms and conditions and to apply them in accordance with the regulations in Bulgaria. Final documentation of good bee keeping practice as regards biological bee keeping is conducted by a certifying organization in Bulgaria.

1.5 Scope

The right to produce using the reference for the production of quality and safe bee products is valid for the whole territory of Bulgaria respecting the principle of territorial continuity and fulfilling these terms and conditions.

2. LEGAL FRAMEWORK OF BIOLOGICAL BEE KEEPING IN BULGARIA

MINISTRY OF AGRICULTURE AND WOODS, MINISTRY OF ENVIRONMENT AND WATERS REGULATION? 35/2001

for the biological production of animals, animal products, and foodstuffs of animal origin and their labeling

Chapter VIII

Bee keeping and bee products

Article 56. Wherever a producer has several bee families on one territory, all bee families are bred in compliance with the rules for biological production.

- Article 57. (1) Bee honey and bee products are sold as produced in a biological manner if only the rules for biological production are complied with within at least one year.
- (2) During the preceding period the wax is changed pursuant to Article 72.
- Article 58. (1) For selecting bee breeds, the producer takes into consideration the accommodation of the breed to local conditions, its viability and resistance to diseases and enemies.
- (2) For the selection as per paragraph 1 herein, the European breeds Apis mellifera and their local ecotypes are preferred.
- Article 59. (1) Bee families are created by multiplication of the existing bee families or addition of bee families from farms with biological production.

- (2) With regulatory permission, the bee families in the farm, which are not bred in compliance with this Regulation can undergo a transition period.
- (3) Bee families in the farm with biological production can be renewed and recovered by bee families from a farm with non-biological production, wherever:
- 1. There are no bee families complying with the requirements of this Regulation;
- 2. There is high bee family mortality due to health reasons or natural disasters in farms in transition.
- (4) Every year 10% of the bee families can be replaced by queen-bees and bee families originating from the farm, which has not introduced the biological manner of production provided that queen-bees and bee families are accommodated in beehives with honeycombs of wax bases taken from biological production. In this case no transition period is required.
- Article 60. (1) Apiaries are situated in regions with sufficient honey-yielding vegetation as a source of natural nectar, honey-yielding dew and pollen and in proximity of water.
- (2) Within a radius of 3 km from the site of the apiary, the sources of nectar and pollen there should consist of biologically produced vegetation or wild vegetation.
- (3) Apiaries should be at sufficiently great distance from any source of possible pollution.
- (4) The requirements as per paragraphs 1, 2, and 3 are not applicable to regions, where blossoming is not possible or wherever bee families are not in active condition.
- Article 61. (1) At the end of the production period, beehives must be left with reserves of honey and pollen sufficient for feeding the bees throughout winter.
- (2) Artificial feeding of bee families is permitted wherever beehives' survival is threatened due to unfavourable climatic conditions. Artificial feeding is done by biologically produced honey preferably of the same produce.
- (3) The regulatory authority permits artificial feeding with biologically produced sugar syrup or sugar molasses, wherever honey crystallizes due to climatic reasons.
- (4) Bee honey and bee product manufacturers keep diaries for the beehives entering data about the type of food, dates, quantities and beehives, wherever artificial feeding is applied.
- (5) For biological production the use of products other than those mentioned in paragraphs 1, 2, and 3 is not permitted.
- (6) Artificial feeding is only permitted between the last honey yield collection and 15 days prior to the next period of nectar and honey-yielding dew collection.

Article 62. The following measures should be taken for the prophylaxis of bee diseases:

- 1. selecting productive and disease resistant bee breeds and lines;
- 2. application of regular care of the bee families according to the season of the year by:
- a) replacement of queen-bees, if required;
- b) regular examinations of the bee families for early establishment of diseases;
- c) control of drone brood;
- d) maintaining good hygienic and veterinary-sanitary condition of the apiaries and auxiliary premises thereto, as well as conducting regular prophylactic disinfecting and disinfections of the bee-breeding equipment;

- e) destruction of contaminated materials and sources of infection, as well as conducting final disinfections in due time:
- f) regular replacement of wax honey-combs;
- g) regular maintenance of sufficient number of honey-combs with honey and pollen in the beehive:
- h) putting away beehives for the winter with sufficient quantities of honey and pollen for the normal bee families passing of the winter.
- Article 63. Upon finding contagious or parasitic disease of bee families, the owner should ensure veterinary-medical treatment, whereas in case of contagious disease treatment should be combined with apiary quarantine.
- Article 64. (1) For treatment of biological production the following veterinary-medical preparations should be used:
- 1. phyto-therapeutic drugs (herbal extracts and essences excluding antibiotics);
- 2. homeopathic drugs (herbal, animal, or mineral);
- (2) Wherever the drugs as per paragraph 1 are inefficient for the fight against diseases and parasites and there is a threat for bee family perishing, the veterinary doctor applies chemically synthesized allopathic veterinary-medical products and antibiotics.
- (3) Use of chemically synthesized allopathic veterinary-medical preparations and antibiotics for disease prophylaxis is prohibited.
- (4) after the use of chemically synthesized allopathic veterinary-medical preparations all wax honey-combs are replaced by new wax based frames originating from the biological production farm and the treated bee families are subjected to a transition period of one year.
- (5) The requirement as per paragraph 4 herein does not apply to treatment of bee families with formic acid, acetic acid, oxalic acid, and menthol, thymol, eucalyptol or camphor in case of Varroa jacobsoni parasite contamination.
- Article 65. (1) Apiary owner must have health passport, where the veterinary doctor enters the following data:
- 1. diagnosis;
- 2. type of the applied veterinary-medical preparation including listing its pharmacologically active ingredients;
- 3. dose of the applied preparation;
- 4. method of application;
- 5. quarantine period of the applied preparation;
- (2) Data as per paragraph 1 is declared before the regulatory authority prior to the submission of bees and bee products on the market as produced by biological method.
- Article 66. In the occurrence of extreme situation in the region on the territory of which the apiary is situated, the mandatory measures for prophylaxis and disease elimination pursuant to the Veterinary Medical Activity Act should be applied.

Article 67. It is prohibited to:

- 1. kill bees in bee-combs as a method for production of honey and other bee products;
- 2. clip the wings of queen-bees and other crippling of bees;
- 3. use of synthetic repellents during honey extraction operations.

Article 68. (1) It is permitted to kill the old queen-bee whet it is to be replaced by a new one.

(2) it is permitted to kill the male generation in order to limit Varroa jacobsoni infection.

Article 69. Any move of the apiary should be co-ordinated with the regulatory authority.

Article 70. The producer should enter in the diary as per article 61 paragraph 4 any action of taking combs out and extracting the honey.

Article 71. (1) Beehives and honey production equipment are made mainly from natural materials, which do not present risks of contamination of environment and bee products. (2) Only natural products such as propolis, wax, and vegetable oils are used in beehives.

Article 72. (1) Bee wax from the biological farm is used for new foundations.

(2) In case of new housing or during the transition period the regulatory authority may permit the use of wax, which is not obtained in biological production provided that there is no biologically produced bee wax on the market and under the condition that the wax is derived from wax unsealings.

Article 73. It is prohibited to extract honey from honey-combs containing brood.

Article 74. Only the preparations listed in Appendix No. 6 should be used for the protection of frames, beehives, and honey-combs from pests.

Article 75. Physical manipulations with spray and direct flame are permitted.

Article 76. Cleaning and disinfecting of materials, plant, equipment, instruments and preparations used in bee keeping is performed with the preparations listed in Appendix No. 5.

APPENDICES

Appendix No. 5 to Regulation 35/2001

Products permitted for use in cleaning and disinfecting of premises and installations (e.g. equipment, instruments, vessels and devices)

- 1. Potassium and sodium soap;
- 2. Water and steam:
- 3. Lime water
- 4. Lime;

- 5. Quicklime;
- 6. Sodium hypochloride (e.g. bleaching solution);
- 7. Caustic soda;
- 8. Potash (potassium carbonate);
- 9. Hydrogen peroxide;
- 10. Natural plant essences;
- 11. Citric, peracetic, formic, lactic, oxalic and acetic acid;
- 12. Alcohols (e.g. spirit);
- 13. Nitric acid (dairy farm equipment);
- 14. Phosphoric acid (dairy farm equipment);
- 15. Formaldehyde;
- 16. Preparations for cleaning and disinfecting of animal udder and milking equipment Sodium carbonate.

Appendix No. 6 to Regulation 35/2001

Products for fighting insects and other pests in stock-breeding plant and equipment

Name	Description, conditions of use
Bee wax	In fruit-growing during engrafting
Lecithin	Fungicide. Permitted for use only after conducting biological study and registration in the country
Extract (water solution) of Nicotiana tabacum.	Insecticide. Permitted for use only after conducting biological study and registration in the country.
Vegetable oils (mainly mint, pine, cumin)	Insecticide, acaricide, fungicide and germination inhibitor. Permitted for use only after conducting biological study and registration in the country.
Chrysantemum cinerariaefolium extract	Insecticide. Permitted for use only after conducting biological study and registration in the country. The necessity is recognized by the regulatory authority.
Quassia amara extract	Insecticide with repellent action. Permitted for use only after conducting biological study and registration in the country.

Extracts of Derris spp., Lonchocarpus spp., Terphrosia spp.	Insecticide. Permitted for use only after conducting biological study and registration in the country. The necessity is recognized by the regulatory authority.
Preparations based on Bacillus thuringiensis	Only if not genetically modified.
Preparations based on granulous virus	Permitted for use only after conducting biological study and registration in the country. Only if not genetically modified
Diammonia phosphate	Attractant. For meshes.
Pheromones	Attractant. For sexual disorientation. Only in meshes and dispensers.
Copper in the form of cupric hydroxide, cupric oxychloride, cupric sulphate and cupric oxide	Fungicide. Only until 31 March 2002. The necessity is recognized by the regulatory authority.
Potassium soap (soft soap)	Insecticide.
Sulphur-lime solution	Fungicide, acaricide, insecticide. The necessity is recognized by the regulatory authority.
Paraffin oils	Insecticide, acaricide.
Mineral oils	Insecticide, fungicide. Only for fruit cultures, vineyards, olive trees and tropical cultures. Only until 31 March 2002. The necessity is recognized by the regulatory authority.
Potassium permanganate	Fungicide, bactericide. Only for fruit cultures, vineyards and olive trees.
Quartz sand	Repellent.
Sulphur	Fungicide, acaricide, repellent.

Apiary Diary

- Biological apiary diary
- Quarantine apiary diary

Farm Diary for produced bee products

Accounting kit

- Book of expenses of biological apiary;
- Book of income from sales of bee products.

Declaration for location, scope and health condition of the production unit (apiary)

- For registration of biological apiary in conversion
- Annual declaration for active biological apiary
- Declaration and itinerary for practicing mobile bee keeping

TECHNOLOGY OF BIOLOGICAL BEE KEEPING

Biological bee keeping is bee keeping which is practiced in compliance with the conditions of biological production in stock-breeding. The reference for biological production can be used by any bee-keeper who:

- Has submitted an application with the certification organization for the control during the transition of the apiary and in the process of producing bee products;
- voluntarily respects the requirements of there terms and conditions and the legal framework for biological bee keeping in Bulgaria;
- Respects the plan for control of his own production (bee keeping).

These terms and conditions and the requirements for biological bee keeping determine the framework of the technology for biological bee keeping in Bulgaria, which is conformable to the specific conditions in the country and the requirements of the legal regulations.

1 PRODUCTION UNIT. ORIGIN. PERIOD OF CONVERSION.

= Bee-keeper who is willing to practice biological bee keeping in one or more of his apiaries, should file an application and a declaration (item 7.6) in his selected certification organization and the regional division of the State Veterinary Medical Service (SVMS). This declaration evidences the concrete existence of the production unit (apiary).

It contains the location of stationary beehives, locations for passing the winter, locations for mobile bee keeping, locations of quarantine apiary. The declaration filed with the SVMS permits the determination of identification (registration) number of the apiary and beehives.

- = the production unit (apiary) only consists of the declared bee families;
- = the origin of the apiary can be of:
- multiplication of bee families in an existing biological apiary;
- acquisition of bee swarms or hives under the conditions set forth hereafter;
- = development of bee families in the apiary is carried out by:
- multiplication of existing biological bee families;
- acquisition of other biological bee families outside the production unit (documented);
- naked swarms, swarms on biological frames or in conventional beehives (in this case the rules for one-year conversion should apply).
- = period of conversion :
- for naked swarms the life time of the bees (about 3-4 weeks), as from the moment of their arrival in the apiary;

- for swarms on frames up to one year provided that the frames are renewed during this year;
- for conventional beehives one year provided that the frames and wax are renewed during this year;
- conversion duration becomes zero if the bee-keeper totally changes the woodwork and the wax bases for all beehives under the terms and conditions of this technology.

The products produced by beehives in a period of conversion (transition) should not avail of the reference for biological bee keeping (they are not biological). They should be listed in the produce of the apiary - Appendix 7.7.

2 REGION OF BEE KEEPING. FEEDING THE BEES.

- = honey-yielding region:
- the apiary should be situated in a region of organic agriculture of uninhabited region. The possibility to collect bee products from regions treated with pesticides or artificial fertilizers should be avoided;
- the region of bee keeping should encompass at least 3 km;
- = feeding the bees:
- biological bee keeping requires such management of beehives and bee families that accumulates sufficient quantity of honey and pollen so that the bees would not be fed. If feeding is necessitated, it should only be by bee honey;
- for traditional region producing manna honey, feeding by sugar syrup after the baseline and 15 days before the main pollen collection is possible with the permission of the certification authorities.

3 APIARY. IDENTIFICATION. MAINTENANCE.

- = apiaries and hives are identified in accordance with the rules of SVMS;
- = maintenance of the apiary region cleaning from bushes, wild vegetation and weeds to be carried out in a mechanical manner or by the use of preparations listed in Appendices 5 and 6 (item 7.1 and item 7.2).

4 BEEHIVES. MATERIALS. PROTECTION

- = beehives are made of natural or neutral materials with respect to the environment and bee products. Beehive protection is also conducted with neutral (environmentally sparing) means:
- water-soluble ecological paints, paints and lacquers permitted for use in foodstuffs;
- impregnation with bee wax, linseed oil, natural herbal extracts and other mixtures;
- azures and paints on vegetable basis, natural and mineral pigments, aluminium and mineral salts:

Materials based on carbonyl, creosote, phenols, etc are prohibited.

- = cleaning the beehive instruments and frames is carried out by :
- physical means flame, air spray, sunlight, steam, etc.;

- chemicals in accordance of those permitted as per Appendix 6 (item 7.2) sulphur, soda, bleaching liquid, acetic acid, etc.;
- biologicals for fighting wax moth, e.g. Bacilius Thurengiensis.

 Any product obtained by chemical synthesis (e.g. dibromoethylene, paradichlorobenzole, etc.).
- = the wax used in the beehive can be only biological or from building frames, spleens and unsealings (collected in the period during which the beehive is not treated with synthetic medicinal products).

5 PROPHYLAXIS AND VETERINARY CARE

= prophylaxis of bee families in biological apiaries:

- cleaning and disinfecting of instruments;
- destruction of contaminated instruments, particularly when its economic value does not justify disinfecting;
- ensuring sufficient quantity of honey and pollen by selection of the region for bee keeping (ample pollen collection);
- regular and frequent replacement of the wax in the beehives;
- selection of hygienic queen-bees and regular replacement of the queen-bees in the hive.
- = isolation apiary it is established and declared before SVMS and the certification organization. Its main purpose is to keep in isolation beehives, which ate affected by diseases. The number of the beehives should not exceed 20% of the mean two-year number of those in the biological apiary. Treated beehives are temporarily excluded from the biological apiary and enter a period of conversion (minimum one year). The production of these bee-hives is labeled and realized in the sales network as conventional honey.
- = veterinary care :
- given only in the isolation apiary except the regular systematic care for fighting varroatosis and the wax moth;
- law enforcement (The SVMS Act);
- fight with varroatosis -

a/ mechanical disposal of the drone brood

b/ use of antivarroatosis grid, double bottom, etc.

c/ selection of hygienic and acar-resistent bee breeds

d/ use of products listed in Appendix 5 (item 7.1)

e/ products based on organic acids (lactic, formic, oxalic, etc.), essential oils (thymol, menthol, etc.), herbal infusions, etc.:

f/ tobacco, pyrethrum;

g/ vegetal and mineral powders.

6 EXTRACTION OF HONEY. PACKAGING. STORAGE

= yield:

- the yield of bee products, in which bees have died of poisoning or contamination, cannot be biological;
- killing bee-families as a method of obtaining bee products is prohibited;
- the use of chemical agents as repellents is prohibited;
- = extraction and transportation of honey:
- all means of the bee farm, which come in contact with honey, must be made of materials, which do not deteriorate the quality of honey: stainless steel, plastic for alimentary products. The use of ferrous and non-ferrous metal, zinc-coated materials, honey heating systems, which do not ensure regulation of the temperature within the range 40-45⁰?, are prohibited.
- = filtration, packaging:
- liquefying is permitted within the said temperature range (40-45^o?);
- the materials of the packaging equipment should comply with the requirements of the preceding sentence;
- it is preferable to use glass as a consumer packaging;
- during storage use hermetically sealed vessels and do not allow moisturizing, exposition to direct sunlight, overheating, etc.
- = for the production of bee floral pollen use drying temperatures less than 40° ?!, as well as vacuum packs and store under 12° ? in case of long-term storage. The requirements relative to packaging are the same as for honey.
- = Labeling of bee products (other than standard):
- show the floral origin of monofloral honey;
- show the vegetal origin of polyfloral honey;
- certificate and certifying authority;
- the sign for biological product established in Bulgaria (lady-bird on a green leaf)

7 PREMISES FOR PROCESSING, EXTRACTION AND STORAGE OF HONEY

?/ additional notes

The purpose of determining standards for premises for extraction and packaging of honey is to favor the extraction and packaging of safe honey (which is not contaminated with pathogenic bacteria for man) and high quality (pure, without residue, unfermented and unable to ferment).

As regards these requirements, the functioning of bee families in the apiary and the physico-chemical characteristics of honey play role, which must be specified:

- the bee family and the beehive where it is placed are not contaminated with bacteria pathogenic for man;
- various beehive elements frames, magazines, etc. are not carriers of contamination risks and can be brought in the processing and reprocessing premises;
- cleaning frames from honey and wax after the extraction of the honey is done by the bees themselves! The role of the bee-keeper is to regularly replace the wax in the honey-combs and to ensure the cleanliness of the family;

- in addition to the requirement that the bee-keeper should extract only rape honey, he/she should only make use of premises, which do not allow secondary honey "damping" during manipulations.

b/ location of the premises

The premises should be situated in places protected against strong and pungent odors, should have water and sewage installations. In addition:

- no operations for reprocessing honey and pollen should be carried out simultaneously;
- no operations for reprocessing of honey and assembly of frames, wiring, fixing wax bases, which are not related with the processing of foodstuffs, should not be carried out simultaneously;
- movement and transportation of the products should be facilitated and cleaning should be carried out without difficulty.

c/ floor, walls and ceilings

Should be made of moisture resistant materials, which do not allow decay and occurrence of moulds and fungi. These should be easy to clean.

d/ airing, ventilation, drying

The premises should allow airing without access of bees and other insects; should allow expelling bees, which have penetrated or brought from outside. No access of rodent penetration should be allowed.

e/ personnel hygiene:

- the people processing bee products during extraction, reprocessing and packaging should maintain perfect hygiene on the working place;
- smoking and use of strongly odorant substances is prohibited;
- lockers, toilets, facilities for washing with ample water, towels, etc., should be provided.
- Operations by sick people are prohibited.

8 QUALITY INDICES OF BIOLOGICAL BEE PRODUCTS

These are the obligations of the bee-keeper relative to the results achieved from biological production:

- HMF for unprocessed honey maximum 10 mg/kg;
- HMF for processed honey (in jars) maximum 15 mg/kg;
- Water content not more than 18.5%;
- Honey extraction should only be made from honey-combs without brood (there should be no exogenic substances).

9 DOCUMENTS OF THE APIARY. CONTROL.

Control of the biological apiary is effected according to submitted documents evidencing the activity of the apiary and via control inspections on the spot.

- = documents to be submitted in case of inspection:
- Map of the location of the apiary, as well as of the quarantine apiary and the locations for mobile bee keeping it is best to have a large scale regulation map from the agricultural service to allow following possible sources of impact or contamination within a radius of 3 km;

Such cartography allows the bee-keeper to keep ahead of possible risks, and the regulatory authority to monitor risks.

- Declaration for the production unit for SVMS and the certifying authority item 7.6.
- Diary of the biological apiary
- Diary of the quarantine apiary
- Diary of the farm for the produced bee products
- Book of expenses of the biological apiary
- Book of the income of sold bee products.
- = documents related to the activity of the apiary:
- Certificates of analysis of the quality of bee product batches;
- Documents for the bee families and hives;
- Health passport of the apiary;

Documents for the building, the place of the apiary, etc.

REGULATION

for

the veterinary, sanitary and hygienic requirements relative to the production, processing and storage of bee honey and other bee products

Chapter?

Background

- Article 1. (1) This Regulation defines the veterinary, sanitary and hygienic requirements relative to the enterprises producing, processing and storage of bee honey and other bee products, hereinafter referred to as "sites"
- (2) This Regulation applies to the sites where the following activities are conducted:
 - 1. Production and primary processing of bee honey and other bee products;
 - 2. Storage of bee honey and other bee products after primary processing aimed at the control of their quality and safety both as food and raw material for industrial processing;
 - 3. Processing and packaging in commercial packs.
 - (3) The veterinary, sanitary and hygienic requirements relative to the sites apply to:
 - 1. Designing, construction and arrangement of the premises;

- 2. Technological equipment, maintenance and operational regime;
- 3. Permitted activities and procedures in various types of sites.
- (4) The veterinary, sanitary and hygienic requirements relative to the production, processing and storage of bee honey and other bee products apply to:
 - 1. Incoming control of bee honey and other bee products, packing materials washing and disinfecting agents, auxiliary and waste products;
 - 2. Technological process and production control;
 - 3. Packaging, labeling and realization;
 - 4. Traceability of the quality of the finished product up to the place of origin of the raw material;
 - 5. Rights, responsibilities and obligations of natural persons and legal entities from the production until the realization of bee products.

Article 2. The sites for production, processing and storage of bee honey and other bee products should comply with the general requirements of Regulation No. 7 of 08 April 2002? for the hygienic requirements relative to enterprises producing or trading in foodstuffs and with the conditions for production of and trade in quality and safe foodstuffs of the Ministry of Health and the Ministry of Agriculture and Forests (promulgated in the State Gazette 40/2002, amended in the State Gazette 59/2003) as regards:

- 1. Design, construction and arrangement;
- 2. Premises conforming to the technological process;
- 3. Technological equipment;
- 4. Operation and maintenance;
- 5. Storage of products and packing materials.

Article 3. Registration of the sites is effected by the bodies of the State Veterinary Sanitary Control with the participation of representatives of the industry union and the product board pursuant to the Foods Act (FA) (promulgated in the State Gazette 99/1999, amended in the State Gazette 102/2003) according to the order of the Veterinary-Medical Activity Act (VMAA) (promulgated in the State Gazette 42/1999, amended in the State Gazette 83/2003) and this Regulation.

Chapter ??

Veterinary, sanitary and hygienic requirements relative to production and primary processing of bee honey

Article 4. (1) Bee honey and other bee products are only produced by apiaries registered pursuant to the Bee-keeping Act (BA) (promulgated in the State Gazette 57/2003).

- (2) Apiaries mandatory fulfil the requirements relative to the prophylaxis and fight against diseases of bees and bee, good bee-keeping (production) practices, as well as the internal monitoring programme for the control of remains of veterinary-medical preparations (VMP) and contaminating agents from the environment.
- (3) The regional veterinary-medical services keep registers of the producers of bee honey and apiaries.

Article 5. The transportation of honeycombs from the apiary to the site of primary processing is carried out in a manner not allowing additional contamination and access of bees.

Article 6. The equipment unsealing honeycombs, centrifuging and filtration of bee honey is made of materials, which are permitted for contact with foods and are resistant to washing and disinfecting agents.

Article 7. The operation premise and the warehouse for storage of the produced bee honey and other bee products should allow the performance of all activities according to the technological process for primary processing and storage of bee products and waste, as well as for easy cleaning, washing and disinfecting.

Article 8. The produced bee honey and other bee products are stored in new disposable tins, which are well cleaned (and washed), with tightly fitting lids.

Article 9. The produced bee honey:

- 1. Should not contain mechanic admixtures;
- 2. The physico-chemical properties should comply with the Bulgarian State Standard (BSS)/Regulation No. 48 for the order and ways of taking samples and the used methods of analysis (State Gazette 103/2003?.);
- 3. Should be stored at temperature up to 15 ? (25⁰?) and without access to direct sunlight, with clear distinction and marking of separate batches.
- 4. Should be stored in dry clean premises with air humidity up to 80% and in the absence of any other side products or materials.
- 5. The batches should be clearly separated and labeled with data from the production log as per article 11.

Article 10. It is not allowed to produce bee honey and other bee products in one and the same time from different apiaries without prior general cleaning, washing and disinfecting of the site and its equipment.

Article 11. The site for production and primary processing of bee honey and other bee products should keep a production log containing the following minimum information:

- 1. Date of production of the batch of bee honey and other bee products:
- 2. The registration number of the apiary from which the honey-combs are taken;
- 3. Quantity of the batches of bee honey and other bee products;
- 4. Date, quantity, designation, name and registration number of the site in which the bee honey and bee products are transferred for storage and/or processing.
- 5. Type and number of the document which is accompanying the bee honey and/or bee products during their transportation to the place of destination.
- 6. An inspector of the regional veterinary medical service (RVMS) should periodically certify the production log.

Chapter ???

Veterinary, sanitary and hygienic requirements relative to enterprises for storage and/or processing of bee honey and other bee products

- Article 12. (1) The premises for storage of bee honey and other bee products before their processing should be a separate part of the processing enterprise or specially constructed for that purpose.
- (2) the premises in the site should have sufficient capacity for separate storage of any incoming batch of bee honey in view of preventing mixing different containers and loss of their identity.
- Article 13. (1) The site should comply with all requirements for long-term storage of the product within its shelf life, as well as to be equipped with the necessary instruments and devices for taking samples from any single container in the batch.
- (2) Every site there should have a developed system for Good manufacturing Practice certified by the services of the State Veterinary and Sanitary Control (SVSC).
- (3) Every site should have a separate premise for storage of samples with sufficient capacity and limited access.
 - (4) Samples should be stored in the site until:
 - 1. Receipt of the results from laboratory analyses;
 - 2. Submission of the batch for processing;
 - 3. Resolution of disputes between supplier and receiver of the product, if any.

Article 14. Every site for storage and/or processing of bee honey and bee products should have a developed laboratory for the control of the physico-chemical properties of the batches, as well as with capacity to make quick (screening) tests for the presence of misbranding and remains of VMPs.

Article 15. Every site should keep:

- 1. Log of all suppliers, as well as a file with full description of the owner, location and registration number of the apiary;
- 2. Diary for the batches received for storage and/or processing, their destination and direction for processing;
- 3. Diary for the samples sent for analysis and the results obtained.

Article 16. (1) Samples are taken from every supplier in the presence of the concerned parties in the following manner:

- 1. Initial sample an aliquot portion of every container of the batch in quantities between 50 and 150 g.
- 2. Average sample the initial samples are mixed and homogenized.
- 3. Laboratory sample -150-200 g of the average sample are taken for testing.
- (2) Laboratory samples are placed in adequate packs, which allow adequate sealing and signing by the concerned persons.
 - (3) laboratory samples are allocated as follows:
 - 1. One sample for analysis in the laboratory of the site for incoming control;
 - 2. One sample for the supplier/owner of the batch;
 - 3. Two control samples for physico-chemical analysis and control for remains of VMP and contaminating agents from the environment;
- (4) Upon request of one of the parties a sample as per paragraph 3, item.3 are sent for tests in an accredited laboratory in the country or abroad.

Article 17. (1) The laboratories for control of bee are registered and approved for operation pursuant to VMAA and the regulation for its implementation irrespective of their ownership, organization and acknowledgement of competence.

(2) The National Veterinary Medical Service (NVMS) keeps a public register of the laboratories for control of bee honey, which are approved by the Minster of Agriculture and Forests.

Article 18. (1) Acceptance, qualification and storage of the raw materials in the sites for processing of bee honey and bee products are carried out by batches of different producers pursuant to the requirements of Regulation No. 48 for the order and ways for taking samples and methods of analysis used (State Gazette 103/2003), Regulation for the requirements relative to bee honey for human consumption (State Gazette 85/2002), Regulation No. 25 for determining the maximum permissible limits for remaining quantities of pharmacologically active substances from the content of VMP in raw materials and products of animal origin intended for human consumption (State Gazette 94/2002) and Article 24 of the Bee-keeping Act

- (2) After qualifying the batch and in accordance with the obtained laboratory results, the batch is realized for:
 - 1. Processing and packaging as food for direct consumption on the domestic market or for export;
 - 2. Processing and adding to other foodstuffs as sweetener;
 - 3. Processing and obtaining other technical raw materials and products.
- (3) Acceptance for processing of raw materials, which show deviations in the quality indices regulated in the normative acts as per paragraph 1.

Article 19. Realization of bee honey and bee products in the commercial network of the country or for export without technological processing in processing enterprises is not permitted.

Chapter ?V

Veterinary, sanitary and hygienic requirements relative to enterprises for processing of bee honey and other bee products

Article 20. (1) Bee honey and bee products are processed in enterprises, which have received veterinary-medical permit for conducting the activities as per Article 57, item 8 of VMAA and Article 92 of the regulation for its implementation (State Gazette 55/2000)

- (2) Enterprises for processing of bee honey and bee products, which produce for export, are registered pursuant to Article 94 paragraph 1 of the regulation for the implementation of VMAA.
- (3) Enterprises for processing of bee honey and bee products, which do not comply with the requirements of this Regulation, do not receive permit as per VMAA. The produce of such enterprises do not bear the health marking and trade in such products for the purposes of human consumption or for industrial purposes is prohibited.

Article 21. (1) Enterprises, which process, bee honey and bee products are designed, constructed and arranged in a manner ensuring separation of two areas – for production and servicing.

- (2) The access of the personnel working in the production area is through a sanitary living filter .
 - (3) The production area is arranged in a manner ensuring:

- 1. Work premises with dimensions ensuring the work under hygienic conditions and situation ensuring continuity of the technological process, which would not allow mutual harmful impact of raw materials, finished produce and waste.
- 2. Warehousing and equipment for separate storage of raw materials, packing and auxiliary materials and finished produce.
- 3. Sanitary-living premises wit established conditions for maintenance of the personal hygiene and a premise for rest of the personnel.
- 4. Auxiliary premises for storage of cleaning instruments, washing and disinfecting preparations.
- (4) Construction of other groups of functionally associated premises is permitted.
- (5) The servicing area is designed, constructed and arranged in accordance with the sanitary-hygienic requirements.
- Article 22. (1) A fence not allowing access of people and animals should enclose the yards of the enterprises.
- (2) It is allowed to construct in the yard of the enterprise only buildings and equipment associated with the concrete production./
- (3) Roads, alleys and platforms in the yard should be paved with asphalt or floored with hard and durable covering, allowing their efficient cleaning with a constructed system for leading surface waters away.
- (4) Buildings are designed and constructed in a manner ensuring overall protection against invasion of pests and bees.
- Article 23. (1) The technological process of the enterprise is arranged in continuity, which would not allow harmful interaction and cross contamination between raw materials, finished produce and waste.
- (2) The technological process uses equipment, which warrants the production of quality and safe product.
- (3) It is not permitted to move semi-finished product in various stage of the production process along open installations.
- Article 24. (1) The technological equipment, which is in immediate contact with the product includes:
 - 1. Heating installations for thermal processing of bee honey;
 - 2. Pipelines for moving semi-finished and finished product;
 - 3. Equipment for filtering and homogenization of bee honey.
- (2) The technological equipment should be made of materials, which do not interact with the product do not change its physico-chemical composition, do not irradiate toxic substances and odour, do not give side taste, are resistant to corrosive action, cleaning and disinfecting.
- (3) The inner surface of the equipment as per paragraph 1 should be smooth and not painted.
- (4) The equipment and its parts and elements are kept clean and in technical operability.
- (5) The technological equipment is installed in a manner allowing access for efficient cleaning of the space around it.

- Article 25. All refrigerators and heating installations are equipped with control thermometers with reading or recording devices.
- Article 26. (1) The technological equipment, which is in immediate contact with the food product, is subject to co-ordination with the State Veterinary Sanitary Control.
- (2) In case of additional installation of technological equipment during operation of the enterprise, the order as per paragraph 1 should be respected.
- Article 27. (1) A system for Good Manufacturing Practice should be developed and implemented in enterprises for processing of bee honey, which should be approved by the SVSC in accordance with the specificity of the technological process and inn respect of the basic principles and warranting the production of a safe product.
 - (2) The basic principles of Good Manufacturing Practice apply to:
 - 1. Safety of drinking water used in the enterprise
 - 2. Waste management;
 - 4. Maintenance of the hygiene in the sanitary-living and production premises;
 - 5. Protecting the product from foreign substances;
 - 6. Cleanliness of contact surfaces;
 - 7. Maintenance and calibration of the technological equipment;
 - 8. Storage of washing and disinfecting preparations;
- 9. Transportation, incoming control and storage of packing materials, raw materials and finished produce;
- 10. Control of the technological procedures and outgoing control of the finished produce;
 - 11. Personal hygiene and training of the personnel;
 - 12. Pest control:
 - 13. Traceability and withdrawal from the market of finished produce.
- Article 28. (1) Access of foreign persons, who do not have association with the activity of the enterprise to the warehousing and production premises is not permitted.
- Article 29. (1) All surfaces of the equipment and installations, which enter in contact with the product are cleaned, washed and disinfected after each use.
- (2) Washing and disinfecting is carried out with duly intended washing and disinfecting preparations ? , which do not harm the equipment, raw materials and finished produce.
- (3) Washing and disinfecting preparations are applied as instructed by the manufacturer.
- (4) Cleaning and disinfecting instruments, washing and disinfecting preparations are stored separately in designated auxiliary premises.
- (5) Written instructions pertaining to the order and method of cleaning, washing and disinfecting, as well as the responsible person's name, are placed at accessible places in the enterprise.
- Article 30. (1) Current and preventing pest control should be carried out in the enterprises.
- (2) Should pests occur, measures for their elimination should be carried out only by the specialized services respecting all necessary measures for non admission of contamination of the equipment, raw materials, and finished produce.

- (3) The measures as per paragraphs 1 and 2 are certified by a written document issued by the specialized service.
- Article 31. High personal hygiene should be respected in the enterprises processing bee honey.
- Article 32. (1) Every person involved in the production process and having contact with the food product is subject to preliminary and periodical medical examinations in compliance with the requirements of Regulation No. 53 for the medical examinations of the persons enrolling and working in catering establishments and public utilities (State Gazette 8/1979; amended, State Gazette 101/1995)
- (2) Persons, who are sick or have contact with persons with gastrointestinal disorders, inflammatory diseases of the upper respiratory tract are not permitted to work.
- (3) The persons as per paragraph 2 are obliged to notify their line management in due course.
- Article 33. Instructions containing the order and conditions for maintaining personal hygiene should be placed in the premises of the enterprise.
- Article 34. Enterprises develop annually personnel training programmes with respect to the measures for the production of quality and safe finished produce intended for human consumption.
- Article 35. (1) Incoming control of packaging materials and the accompanying documentation is performed by a duly designated person from the staff prior to their acceptance in the enterprise.
- (2) Enterprises accept only packaging materials complying with the requirements of Regulation No. 1 for materials and objects made of plastic and intended for contact with foodstuffs (State Gazette 13/2002) and Regulation No. 24 for the hygienic requirements for materials and objects different from plastic and intended for contact with foodstuffs (State Gazette 56/2001; amended, State Gazette 13/2002).
- (3) The persons as per paragraph 1 enter the received packaging materials in the register for incoming control after every delivery.
- (4) the register as per paragraph 3 contains the following data: day of delivery; name of manufacturer; type of packaging materials; type of documentation accompanying the packaging materials, claims; signature of the designated person.
- Article 36. (1) Packaging materials are stored separate from raw materials and finished produce in dedicated for this purpose premises under conditions, which do not allow contamination and damage.
- (2) Storage of packaging materials outside the warehousing premises is prohibited.
- (3) It is not permitted to store packaging materials with other non-alimentary and alimentary products, which are not related to the production process.
- (4) Warehousing premises for packaging materials are maintained clean and tidy at any time.
 - Article 37. Multiple use of packaging materials for finished produce is prohibited.
- Article 38. (1) For transportation of raw materials and finished produce are used clean vehicles, which are maintained in good order, with construction allowing efficient cleaning and disinfecting.

- (2) Transportation is carried out only with transport vehicles possessing certificates as per Article 98, paragraph 2 of the Regulation for the implementation of VMAA.
- (3) Raw materials and finished produce are placed in the transportation vehicles in a manner minimizing the risk of contamination.
- (4) Joint transportation with other alimentary and non-alimentary products, which are not directly related to the production process, is prohibited.
- Article 39. Technical documentation is prepared for the finished produce and a register is kept as per Article 56, paragraphs 1 and 2 of Regulation No. 7 of the Ministry of Health and the Ministry of Agriculture and Forests of 08 April 2002 (State Gazette 40/2002; amended, State Gazette 59/2003).
- Article 40. Enterprises processing bee honey accept only bee honey batches /from apiaries where ... / accompanied by documents of RVMS containing the following data:
 - 1. No antibiotics and sulphonamides are used during bee and bee brood breeding;
 - 2. No admixtures misbranding and imitating the products are added;
 - 3. There is registration pursuant to the Bee-keeping Act;
 - 4. There are no registered infectious diseases.
- Article 41. (1) Bee honey and other bee products are accepted in packaging compliant with the requirements of Regulation No. 1 for materials and objects made of plastic and intended for contact with foodstuffs (State Gazette 13/2002) and Regulation No. 24 for the hygienic requirements for materials and objects different from plastic and intended for contact with foodstuffs (State Gazette 56/2001; amended, State Gazette 13/2002).
- (2) Packaging, in which the raw materials are accepted, are disposable, clean, without corrosion and with tightly closed lids.
- Article 42. Production batches are formed from the batches of bee honey received for processing.
- Article 43. (1) During the processing of the formed batches enterprises obligatorily carry out production control as regards:
- 1. Storage of raw materials and finished produce under temperature not exceeding 15⁰? *and humidity up to 80%*. These characteristics are entered on a daily basis in the Temperature Log, which contains the following data: name of the premise; measured temperature values; name and signature of the responsible person.
- 2. The temperature of the thermal processing of bee honey should not exceed 50° ? *air temperature*. These readings are registered in the Production Chart, which contains the following data: date; batch number; batch quantity; maximum temperature attained during thermal processing, name and signature of the responsible person.
 - (2) Adding of admixtures, imitating and misbranding of bee honey is prohibited.
- Article 44. (1) Enterprises obligatorily carry out outgoing control of the finished produce for quality and safety compliance, including:
- 1. Analysis for presence of <u>pathogens/</u> microorganisms, which are pathogenic to bees and bee brood.
 - 2. Physico-chemical and organoleptic analysis.
 - 3. Analysis for presence of remaining quantities of VMPs.

(2) Qualification and storage of the finished produce is carried out by production batches.

(3) Accredited laboratories carry out analyses as per paragraph 1.

Article 45. Enterprises for processing bee honey obligatorily keep a Register for the outgoing control of the raw materials containing the following data: date of production; registration number of manufacturers included in the batch; batch number; quantity of the finished batch; numbers of protocols for laboratory analysis; results from laboratory analysis.

Article 46. (1) The manager of the enterprise is obliged to designate a person responsible for the Good Manufacturing Practice (GMP).

(2) The responsible person as per paragraph 1 conducts monitoring, control and analysis of the GMP system and suggests adequate measures for the production of a product, which is safe for human consumption.

Article 47. (1) The manager of the enterprise is obliged to define and implement procedures for conducting monitoring and control of the activities of the enterprise in compliance with the requirements of this Regulation warranting the production of a safe product.

- (2) Implementation of the procedures for monitoring and control is documented in writing.
- (3) The information as per paragraph 2 is kept for 3 years and is submitted for inspection upon request of the regulatory authorities.

Article 48. Products labeled pursuant to the Regulation for the requirement for labeling and presentation of foodstuffs (State Gazette 100/2003 ?.)

Article 49. Enterprises should have a developed written system for overall traceability, which warrants quick and timely withdrawal of products,, which do not comply with the safety criteria, from the market.

Article 50. Beeswax is accepted by batches pursuant to the requirements of BSS 13143-80 "Beeswax".

- 1. Beeswax is a raw material and finished product and is stored in separate premises dry, clean and protected against bees, pests and products emitting odours.
- 2. Workshops for processing beeswax and production of wax bases should be separate and access to other bee products should not be permitted.
- 3. For the production of wax bases beeswax must be thermally processed at temperature 120°? for 60 minutes.

Article 51. Royal jelly natural is accepted in glass bottles by batches with ensured temperature from -5 to 0° ? in the apiary, transport vehicle and processing enterprises at the moment of acceptance and in compliance with the requirements of its technical documentation.

- 1. During long-term storage but not more than 3 years, royal jelly should be stored in a dark place at temperature from -20 to -15°?.
- 2. In commercial packaging made of glass royal jelly is stored for not more than 1 year at temperature from -5 to 0° ?

- 3. Freeze-dried royal jelly is stored in two-layer polyethylene bags with black outer layer and opaque white inner layer, hermetically closed, at temperature from -5 to 0° ?
- Article 52 Bee pollen is accepted by separate batches in compliance wit the technical documentation and is stored up to 1 year in apiaries and processing enterprises in dry and clean premises at temperature from -5 to 0° ?
- 1. Bee pollen is packed in hermetically closed polyethylene bags, aluminum foil of other type of packaging approved for alimentary purposes.

Article 53 Bee clay is accepted by separate batches in compliance with the technical documentation. It is stored in dry, clean, dark and aerated premises for not more than 7 years at temperature up to 15°?. It is packed in polyethylene, paper or other approved packaging, which does not contaminate the product.

ADDITIONAL PROVISIONS

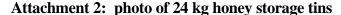
§ 1. In the sense of this Regulation:

- 1. "Bee honey", respectively "honey" is a nutritional, viscous, liquid or crystallized product produced by honey-bees from the nectar of flowers or secretions from or on the live parts of plants, which honey-bees collect, transform, combine with concrete substances, which they secrete, store and leave to ripe wax honey-combs.
- 2. "Beeswax" is a product, which worker bees secrete through their wax-yielding glands.
- 3. "Royal jelly" is a product secreted by the hypopharyngeal (throaty) and mandibular (upper jaw) glands of bees.
- 4. "Freeze-dried royal jelly" is a product obtained through freeze-drying (lyophilization) of natural royal jelly in vacuum at low temperatures.
- 5. "Flower bee pollen" is a product collected by honeybees from the flowers of plants and taken from the baskets of bees through pollen catcher.
- 6. "Bee clay" is a product, which bees collect from the resinous substances of the buds of trees.
- 7. "Primary processing of bee honey" is unsealing honeycombs, centrifuging, filtering and packaging of bee honey in transport packs.
- 8. "Batch" of bee honey is the product obtained by one-fold primary processing of honeycombs from one apiary.
- 9. "Production batch" is a aggregate of several batches of bee honey processed simultaneously, with equals quality parameters and packaged on one and the same consumer packs.
- 10. "Enterprise for processing of bee honey" is a site in which a general or partial processing, packaging, labeling and storage of bee honey and other bee products is taking place.
- 11. "Processing" is thermal or otherwise transformation of bee honey in liquid state, homogenization, filtration or mixing of bee honey, as well as rendering

- other bee products in a state fit for use for industrial, respectively production purposes and/or human consumption.
- 12. "Technological equipment" is machines, equipment, installations, vessels, work broad boards and auxiliary instruments used at various stages of the production process.
- 13. "Packaging materials" are consumer packs, in which the finished produce reaches its final consumer, including packaging for the storage and transportation of bee honey and other bee products for industrial use.
- 14. "Health marking" is information in oval design, which contains the veterinary registration number of the producer and the capital letters.
- 15. "Traceability" is the possibility to trace the quality of the finished produce in all stages of production and trade up to the place of origin of the raw material.

TRANSITIONAL AND CLOSING PROVISIONS

- § 2. This regulation is issued on the grounds of Article 22, paragraph 3 of the Beekeeping Act and Article 17, paragraph 2 of the Foods Act.
- § 3. Control of the enforcement of this Regulation is conducted by the bodies of the State Veterinary Sanitary Control pursuant to Article 28, paragraph 1 of the Foods Act with the participation of the industry union and the product board.
- § 4. This Regulation is effective as from 01......2004?.





Attachment 3: Photo of 300 kg honey storage barrels

